

Appl. No. 10/615,727
Amd. Dated May 31, 2005
Reply to Office Action of December 1, 2004

REMARKS

Claims 1, 6, 7, 10, 11, 13, 14, 34-50, 54, 55 and 58-74 are currently pending in this application. Claims 1, 34, 37, 39, 41, 62, 67, and 72-74 are currently amended. Reconsideration is respectfully requested in view of the following remarks.

Allowable Claims and Suggestion of Interference

Applicant acknowledges that the Examiner has allowed claims 44-50, 54, 55, and 58-61. These claims were copied from US Patent 6,565,605. Applicant will separately file a suggestion of interference in accordance with 37 CFR 41.202 between the allowed claims 44-50, 54, 55, and 58-61 and the corresponding claims copied from US Patent 6,565,605.

I. Claim Rejections Under 35 USC § 112, First Paragraph and 35 USC 102(b) to Goble

The Examiner rejected claims 34-43 and 67-70 under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. Applicant has replaced the term "the posterior arch" with the term "the lamina" so that the claims comport to the anatomical terms and description in the specification.

Vertebral anatomy in the present application is set forth with regard to FIG.

28.

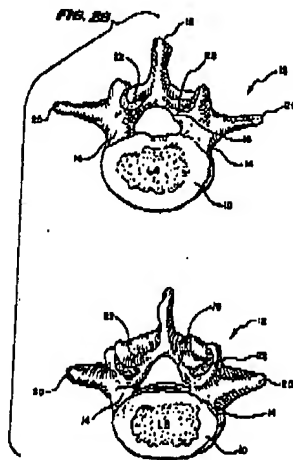


FIG. 28 is described, in relevant part, in the specification on page 10 lines 4-24 as:

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"The vertebral arch 12 is posterior to the vertebral body 10 and is formed by the right and left pedicles 14 and lamina 16. The pedicles 14 are short, stout processes that join the vertebral arch 12 to the vertebral body 10. The pedicles 14 project posteriorly to meet two broad flat plates of bone, called the lamina 16."

Claims 34, 37, 39, 41, and 67 have been amended to delete the term "said posterior arch" and replace it with "the lamina." Support for this amendment is found in the specification and figures and no new matter has been added. Applicant requests that the rejection of claims 34-43 and 67-70 under 35 USC §112 first paragraph be withdrawn.

Currently amended claims 34-43 and 67-70 are fully supported by the specification of the parent application 09/693,272 filed October 20, 2000. Goble 6,579,319 was filed on November 29, 2000 after the present application and is not a valid prior art reference. Because Goble is not a valid prior art reference the rejection of claims 34-43 and 67-70 under 35 USC §102(b) in view of Goble should be withdrawn.

II. Claim Rejections Under 35 USC § 102(b)

Rejections under Martin (6,132,464) or Fitz (RE 36,758)

The Examiner also rejected claims 1, 6, 7, 10, 11, 13, and 14 under 35 USC § 102(b) as being anticipated by either of Martin (6,132,464) or Fitz (RE 36,758).

The Examiner has previously considered and allowed claims over both Martin and Fitz in the related cases Reiley US 6,610,091 and Reiley US 6,811,567. The instant case claims the benefit of the filing date of Reiley US 6,610,091.

Currently amended claim 1 recites, in relevant part:

"an artificial left facet joint structure on the left prosthesis body adapted and configured to replace a cephalad portion of the left natural facet joint after removal of a portion of the vertebral arch, and

an artificial right facet joint structure on the right prosthesis body adapted and configured to replace a cephalad portion of the right natural facet joint." Support for the claim limitation relating to the removal of a portion of the vertebral arch, as claimed in amended claim 1, is disclosed in

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Applicant's Specification on, at least, page 15 lines 24 – 34, page 17 line 23 – page 18 line 1, and page 20 line 28 – page 21 line 8.

Neither Fitz nor Martin teach or suggest a prosthesis to replace a cephalad portion of a left natural facet joint on a vertebral body and a cephalad portion of a right natural facet joint on the vertebral body, the prosthesis comprising an artificial left facet joint structure on the left prosthesis body adapted and configured to replace a cephalad portion of the left natural facet joint after removal of a portion of the vertebral arch, and an artificial right facet joint structure on the right prosthesis body adapted and configured to replace a cephalad portion of the right natural facet joint. In Fitz, no portion of the vertebral body is removed. Indeed, Fitz requires the presence of the natural articular processes to support his prosthesis, which resurface (but do not remove) the natural articular processes. Martin, too, teaches the use of a prosthesis to resurface (but not remove) a natural articular process, and no where teaches, describes or suggests the removal of any portion of a vertebral body. Neither Fitz nor Martin contemplate or appreciate the attendant benefits of the removal of anatomical elements, e.g., alleviation of pain and the ability to create an artificial facet joint that is not constrained by preexisting articular configurations. For at least the reasons set forth above, neither Martin nor Fitz anticipate newly amended claim 1 which is now allowable. Pending claims 6, 7, 10, and 11 all depend from claim 1 and are therefore also not anticipated by Martin or Fitz. As such, claims 6, 7, 10, and 11 are allowable. Pending method claim 13 recites using the prosthesis of claim 1 so it too would not be anticipated by Martin or Fitz. Pending claim 14 depends from allowable claim 13. Claim 14 is now allowable.

Rejections under any of Laure, Johnson, and Lewis

The Examiner also rejected claims 62, 63, and 66 under 35 USC § 102(b) as being anticipated by any of Laure (4,040,130), Johnson, et al (4,156,296), and Lewis (4,231,121).

Applicant previously presented claims 62 to 74 that were, respectively, copied from claims 1-4 and 8-16 of US Patent Application Ser. No. 10/421,078 published as US Patent Application Publication US 2003/0191532. Based on information available from the USPTO Public PAIR system, Applicant has learned that a preliminary amendment filed in Patent Application Ser. No. 10/421,078 canceled all claims that were previously copied in the instant case. Applicant further points out that the preliminary amendment canceled all 16 previously pending claims and presented

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new claims 17–36. The applicant in Patent Application Ser. No. 10/421,078 has not merely replaced the original claims with updated versions of the claims. Instead, the applicant in Patent Application Ser. No. 10/421,078 had filed claims related to a prosthesis and fixation method that connect independent of penetration into the pedicle and a prosthesis and fixation method that connect by penetrating a portion of the lamina.

Independent claim 62 is presently amended and now reads:

A prosthesis for the replacement of at least a portion of the bone of a facet located on a mammalian vertebra, comprising: a surface that articulates with another facet surface; a fixation portion that is configured for implantation [implanted] into an interior bone space of said vertebra, said surface being connected to said fixation portion.

Laure, Johnson and Lewis are unrelated to any form of prosthesis for the replacement of at least a portion of the bone of a facet located on a mammalian vertebra. Laure is related to a prosthesis for a wrist. Johnson is related to a metacarpal-phalangeal prosthesis. Johnson is related to a great toe prosthesis. Neither Laure, Johnson nor Lewis have anything to with a prosthesis related to vertebra - or any portion of the spine for that matter – and thus they provide no teaching, suggestion or description of a fixation portion that is configured for implantation into an interior bone space of a vertebra as required by presently amended claim 62. As such, none of Laure, Johnson or Lewis can anticipate independent claim 62. Claim 62 is therefore allowable as are claims 63 – 66 that depend from allowable claim 62.

III. Claim Rejections Under 35 USC § 103(a)

The Examiner rejected claims 64 and 65 under 35 USC § 103(a) as being unpatentable over any of Laure, Johnson, and Lewis as applied to claim 62, and further in view of Brosnahan III (5,766,253).

Rejected claims 64 and 65 depend from independent claim 62. Claim 62 is presently amended and is allowable over Laure, Johnson and Lewis for at least the reasons set forth above. Because neither Laure, Johnson, nor Lewis have anything to with a prosthesis related to vertebra - or any other portion of the spine for that matter – they provide no teaching, suggestion or description of a fixation portion that is configured for implantation into an interior bone space of a vertebra as required by presently amended claim 62. Brosnahan, on the other hand, is related to spinal fusion

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and implanting one or more fusion devices 10 into the spinal column to fuse adjacent spinal vertebra (Col. 3 lines 22-30, Col. 4 lines 18-23 and FIGs. 1, 2 and 3). Applicant suggests that the proposed combination of Brosnahan with any of Laure, Johnson or Lewis is improper. One of ordinary skill considering the spinal fusion device of Brosnahan would have no motivation what so ever to consider, combine or modify that device based on Laure's wrist prosthesis, Johnson's finger and toe prosthesis or Lewis's big toe prosthesis. Moreover, even if some motivation to combine these references could be identified, such a combination would fail to render amended claim 62 obvious because any such combination would still lack any suggestion of "a surface that articulates with another facet surface." Laure, Johnson or Lewis are unrelated to the spine and make no mention of facet surfaces. Brosnahan describes only spinal fixation, which is the antithesis of "a surface that articulates" as required by amended claim 62. For at least these reasons, no combination of Laure, Johnson, Lewis or Brosnahan can render obvious amended claim 62. Claim 62 is therefore allowable as are dependent claims 63 - 66 that depend from allowable claim 62. As such, the rejection of claims 64 and 65 under 35 USC 103 should be withdrawn.

CONCLUSION

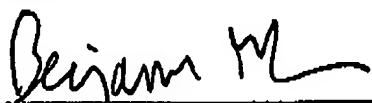
In light of the remarks set forth above, Applicant has responded to all rejections presented by the Examiner and believe that all pending claims (i.e., claims 1, 6, 7, 10, 11, 13, 14, 34-50, 54, 55 and 58-74) are in condition for allowance which is respectfully requested.

Should the Examiner have any questions regarding this reply or application, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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